



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 7, 2012, from 8 a.m. to 5:30 p.m. and May 8, 2012, from 8:30 a.m. to 11:30 a.m.

Location: Hilton Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Walter Ellenberg, Office of Pediatric Therapeutics, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993, 301-796-0885, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough

to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 7, 2012, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, for Differin Lotion (adapalene), Dulera Inhalation Aerosol (mometasone furoate and formoterol fumarate), MultiHance Injection (gadobenate dimeglumine), Nasonex (mometasone furoate monohydrate), Natazia (estradiol valerate and estradiol valerate/dienogest), Omnaris Nasal Spray (ciclesonide), Protonix (pantoprazole), Tamiflu (oseltamivir phosphate), Taxotere (docetaxel) and Viread (tenofovir disoproxil fumarate). The committee will also receive an Informational Update on FDA's KidNet pilot study.

On May 8, 2012, the Pediatric Advisory Committee will meet regarding the pediatric-focused safety reviews, as mandated by the Pediatric Research Equity Act, for Gardasil Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant, Isopto Carpine (pilocarpine hydrochloride), Menveo Meningococcal (Group A,C,Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine, Zylet (loteprednol etabonate and tobramycin) and Zymaxid (gatifloxacin).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at

<http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 30, 2012. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on May 7, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 20, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 23, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: March 23, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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